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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,557	08/22/2001	Erik Gunther	GUNE117293	8854
26389	7590	10/06/2004	EXAMINER	
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/935,557

**Applicant(s)**

GUNTHER, ERIK

**Examiner**

Ardin Marschel

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12-17 and 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 18-21, & 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date, <u>7/1/04</u> .                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's arguments, filed 7/12/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **INTERVIEW SUMMARY NOT AGREED WITH**

On 7/12/04, applicant has submitted an Interview Summary for the Interview held by telephone on 7/1/04. Applicant's Interview Summary indicates that an agreement was reached that Daniel et al. does not disclose step (c) of the invention of claim 1. This is not agreed with. The Interview of 7/1/04 included a discussion and concern that Daniel et al. may not disclose said step (c) but that the Examiner wished to review Daniel et al. on this point after formal arguments directed to this has been submitted. No agreement as to step (c) was reached at the time of the Interview. This issue and discussion is also reflected in the attached Exr. Int. Summary for 7/1/04 and also indicates that agreement was not reached and that further review of Daniel et al. was desired by the Examiner. The last statement of applicant's interview summary is that two figures would be submitted. This last statement is agreed with as being discussed during said Interview. It is noted that reconsideration of Daniel et al. is described below.

**ABSTRACT**

The abstract of the disclosure is objected to because it exceeds 150 words. A shortened abstract on its own separate sheet of paper is required. Correction is required. See MPEP § 608.01(b).

**VAGUENESS AND INDEFINITENESS**

Claims 1-4, 6-11, 18-21, and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 1-2, the method is directed to discovering compounds with expression profile-altering activity. This contrasts with the steps in instant claim 1 wherein the analyte(s) therein analyzed are identified as being of the type which induces a third expression profile more similar to the first than second profile. Thus, the actual claim steps specifically are not directed to discovering compounds which simply alter an expression profile but rather actually alter it to be more similar to a first profile. Thus, the preamble of claim 1 has a different goal than the actual claim steps. This causes the claim to be vague and indefinite as to whether the preamble requires additional step(s) regarding simple profile altering compounds or whether the metes and bounds of the claim are limited to the actual step (d) practice. This unclarity is also present in claim 32. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 1 or 32 also contain this unclarity due to their dependence.

### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-9, 18-21, 32, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (P/N 6,368,794).

Reconsideration of Daniel et al. reveals that the reference does, in fact, contain a description of step (c) of instant claim 1 in general terms which contains an easily discerned suggestion that is specifically directed to the practice of step (c) of instant claim 1.

To summarize the description of the instant invention in Daniel et al., firstly steps (a) and (b) of instant claim 1 are hereby pointed to in column 10, lines 5-67. In column 10, lines 5-20, the determining of gene expression profiles wherein differing levels of expression are detected and quantitated is set forth. In column 10, lines 54-67, hybridization complexes are described for such determinations wherein a standard value (first expression profile of step a) of instant claim 1) for each signal is discussed which is altered compared to said standard in a disease state which is the second sample profiling practice of step b) of instant claim 1. Column 10, lines 64-67, begins a discussion of utilizing such assays for evaluating the efficacy of a therapeutic regimen. In column 11, lines 1-7, this evaluation practice is clarified in that a treatment protocol is initiated and hybridization assays are repeated to "determine if the level of expression in

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the patient begins to approximate that which is observed in a healthy subject". Such comparisons are also reasonably a difference profile determination as in instant claim 2. Such repeated assays of expression levels after treatment is reasonably step (c) of instant claim 1 when considered in view of what is meant in Daniel et al. regarding treatment. Daniel et al. goes on to state that the results may be used to show the efficacy of treatment over time. The approximation of assay level outcome to a healthy subject is reasonably interpreted as accurately suggesting and motivating step (d) of claim 1 wherein efficacy of treatment causes the expression level to return to the first profile of a healthy subject. Daniel et al. describes what is meant therein for treatment as several citations including column 2, line 65, through column 3, line 5, which is clearly an analyte as instantly utilized in step (c) of instant claim 1. In column 5, lines 27-42, the sequences that may be selected for pharmaceutical compositions are first selected from differentially expressed genes in cancerous or precancerous tissue and thus are uncharacterized at that point as to whether they have any specific pharmacological activity as also a limitation in instant claim 1, step (c). Thus the practice of instant claim 1 is clearly suggested and motivated in Daniel et al. as also inclusive of the Key step shown in applicant's argued Figure depicting the Gunther invention, filed 7/12/04.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the gene expression hybridization assays of Daniel et al. on sequences therein described for healthy as well as diseased subjects and then, following treatment, reassay and compare the expression profiles to

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determine if a healthy type profile has resulted which is the step (d) of instant claim 1 thus resulting in the practice of the instant invention with a reasonable expectation of success. The microarray analysis of instant claim 9 is described at several citations in Daniel et al., for example, in column 5, lines 4-26.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 30, 2004

*Ardin H. Marschel 9/30/04*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER